

U.S. Application No.: 09/926,411  
Reply to Office Action dated August 7, 2003

SUPPORT FOR THE AMENDMENTS

Applicants have amended Claim 6 to recite "ocular administration." Support for amended Claim 6 can be found in the same claim, as originally filed, and on page 11, lines 15-23, of the specification. Applicants have also amended Claim 4 to recite that the "macrolide compound is administered in the form of a preparation suitable for administration as an eye drop." Support for amended Claim 4 can be found in the same claim, as originally filed and on page 12, lines 1-4, of the specification.

No new matter has been added. Claims 2-4, 6, and 8-12 are active in this application.

REMARKS

Present Claims 2-4, 6, and 8-12 relate to a method for treating a dry eye, comprising ocular administration of an effective amount of a macrolide compound to a subject in need of the treatment of dry eye.

The inventors have surprisingly found that ocular administration of a macrolide compound is effective for the treatment of dry eye.

The cited references contain no disclosure or suggestion of the presently claimed methods or agents. Accordingly, these references cannot affect the patentability of the present claims.

The rejection of Claim 24 under 35 U.S.C. § 102(b) in view of Yang et al; the rejection of Claim 24 under 35 U.S.C. § 102(b) in view of Iwamoto et al; and the rejection of Claim 24 under 35 U.S.C. § 112, second paragraph, have all been obviated by appropriate

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amendment. As the Examiner will note, Applicant has canceled Claim 24. Accordingly, these rejections should be withdrawn.

The rejection of Claim 5 under 35 U.S.C. § 112, second paragraph, has also been obviated by appropriate amendment. In this case, Applicant has canceled Claim 5. Again, the rejection should be withdrawn.

The rejection of Claims 2, 3, 5, and 6-12 under 35 U.S.C. §102(b) in view of Sandoz Ltd. has also been obviated by appropriate amendment. As the Examiner will note, Applicants have amended Claim 6 to recite “ocular administration” as suggested at the bottom of page 6 of the Office Action. Accordingly, the rejection is no longer tenable and should be withdrawn.

The objection to Claims 4 and 8 has also been obviated by appropriate amendment. Specifically, Claim 4 has been amended to recite that the “macrolide compound is administered in the form of a preparation suitable for administration as an eye drop.” Thus, the rejection should be withdrawn.

Applicant notes that in the Amendment filed on May 27, 2003, Claim 3 was amended to be multiply dependent. However, the fee for the multiple dependency (\$290.00) and the resultant extra claim (\$18.00) was inadvertently not paid. Accordingly, Applicant is submitting herewith the fee of \$308.00

Lastly, Applicant also notes that an Information Disclosure Statement (“IDS”), along with 25 cited references, was filed on August 7, 2003. However, to date, Applicant has received no confirmation that the Examiner has considered the references submitted with the

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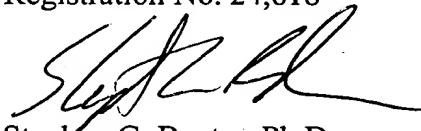
IDS. Accordingly, Applicant respectfully requests that the Examiner confirm that the references submitted with the IDS filed on August 7, 2003, have been considered by returning an initialed copy of the PTO Form 1449 along with the next communication from the PTO.

Applicant submits that the application is now in condition for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

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